

EXHIBIT 8

Brief review of the December 15, 2003 Overview Document and the draft Services letter.
Rachel Friedman
NOAA Fisheries
December 16, 2003

I. TOPICS ADDRESSED IN THE COMMENT LETTER

The Services are basing their conclusions of the ability of OPP's ecological risk assessment process to produce sufficient ESA section 7 effects determinations on proposed modifications identified in the draft letter to Stephen Johnson from Bill Hogarth. A number of items pertaining to how OPP will modify the risk assessment process are not identified in the Overview document (December 15, 2003). In addition, a number of topics have not been addressed, or not addressed with sufficient detail.

Best Scientific and Commercial Data Available. The Overview document did not discuss that OPP would request MED "a). search its holding files for any relevant information identified through its search strategies, but not yet reviewed by MED and made available on ECOTOX; and b) search its files for any relevant information rejected for inclusion by MED".

The Overview document only says that OPP is developing a search strategy for finding and filtering pesticide data in ECOTOX and is establishing guidance on how to evaluate the data output. The letter states that OPP "will utilize broad search strategies". The Services have not seen the search strategies. Nor has OPP described how studies will be accepted or rejected, or what to do when there are conflicting study results.

In addition, NOAA Fisheries has conducted trial side-by-side searches using ECOTOX solely, and using a broader array of databases and have found that, while ECOTOX will provide some data additional to that provided by the registrants, the broader search produced approximately 3 times more documents without any overlaps with ECOTOX. Exclusive use of ECOTOX risks the oversight of best scientific and commercial data, and a subsequent Type II error in effects determination.

Potential Exposure. In 2004, the SAP will be reviewing models that consider variations in water body volume and evaporative loss, and techniques to allow for greater or lesser dilution by surface water runoff into receiving waters. There is no consideration for the potential direction to protect listed resources if the SAP rejects the proposals.

The comment letter identifies that, as a result of different model results for aerial spraying, OPP "intends to identify the margin of error from the use of this model, and to conduct further analysis in any situation where the total exposure calculated falls within this margin of error." This is not addressed in the Overview document.

Levels of Concern. The Overview document did not discuss that calculations an estimate of actual probability from applying the 0.05 factor to the LC50 will be included in the documentation.

Consideration of Pesticide Formulation, Mixtures and Degradates. The facultative nature of case-specific evaluations of formulations has the potential to cause Type II errors of predicting no or limited adverse effects to listed resources. Incorporation of product formulation only if it is available, also risks Type II errors to listed resources.

The Overview document states that EPA's methods for considering formulated product exposure follows approaches developed by the European Union. However, the comment letter states that OPP's approaches for conducting screening level risk assessment of formulated products differs from the EU, and that OPP would obtain and consider such information in its risk assessment.

Critical Habitat. The comment letter confounds the role of EFED and of FEAD. It states that OPP will determine if any portion of the action area has been designated as critical habitat. The topic of action area has not been discussed, nor does EFED address spatially specific effects. Unless FEAD begins conducting site-specific risk assessments based on action areas, as a means to arrive at the initial "no effect" or "may affect" determination and if they do their assessments prior to EFED conducting the screening level assessment, then the evaluation of critical habitat will not be sufficient and Type II errors will proliferate.

II. TOPICS NEVER COVERED AS PART OF THE REVIEW OF EPA'S OVERVIEW DOCUMENT

Given that the Services were forced to identify key topics (11) for discussion with EPA, due to the time requirements for the publication of the counterpart regulations, a number of topics have never been addressed. I have identified a number of procedural, technical and policy issues that remain outstanding.

1. Regulatory Process (III C) - No review occurred beyond the typical section 3 registrations.

A. Experimental use permits (III C 2) - Never had the opportunity to discuss topics such as how ESA-level review and consultation takes place, how the use-specific data differ from section 3 and whether they are sufficient for ESA consultation, length of the permits, potential for locational use restrictions, etc.

B. Emergency exemptions (III C 3) - Never had the opportunity to discuss topics such as what is involved in EPA's " cursory review", what are the triggers for EPA to note concerns, how ESA-level review and consultation takes place, etc.

C. Special local need (SLN) registrations (III C 4) - Never had the opportunity to discuss topics such as what ecological review occurs, how the process for not disapproving of an SLN becomes a section 3 approval, how ESA-level review and consultation takes place, etc.

2. Problem Formulation (V A) - Despite the assertion that OPP conducts a problem formulation exercise at the outset of the risk assessment, they do not structure the assessment based on the ecological questions of potential effects to specific listed species with subsequent identification of specific assessment endpoints and development of a conceptual model as the foundation of the risk analysis evaluating the effects of the registration and use on the species in question.

This is further verified in EPA's acknowledged reliance on the Standard Evaluation Procedures

which describe a tiered method of assessment with a standard suite of toxicity endpoints.

3. Overview of OPP's Species-specific Ecological Risk Assessment Process for Aquatic Life, Wildlife, and Plants (VI) - The Services did not have an opportunity to subject the described FEAD process to the review of the technical committee, senior scientists or program specialists. As a result, it is disingenuous to state that the broad OPP process is capable of producing effects determinations that are consistent with section 7 of the ESA.